



Certificate of Analysis

| | | | |
|------------|-----------------------------|------------------|----------|
| PRODUCT: | CoaTest SP Factor FVIII Kit | PRODUCT #: | 82408663 |
| EXP. DATE: | 2018-12 | LOT #: | N0177412 |
| VENDOR: | INSTRUMENTATION LABORATORY | ASSAYED PER QCM: | 824086 |

| TEST DESCRIPTION | SPECIFICATIONS | | UNITS | RESULTS | DISPOSITION |
|--|----------------|--------|-------|---------|-------------|
| | MIN | MAX | | | |
| Coatest SP Factor VIII Kit (82103363) | | | | | |
| High Range | | | | | |
| Slope | 0.0077 | 0.0112 | -- | 0.0097 | PASS |
| Intercept | -- | 0.250 | -- | 0.115 | PASS |
| Standard Curve (r) | 0.99 | -- | -- | 0.999 | PASS |
| Low Range | | | | | |
| Slope | 0.020 | 0.060 | -- | 0.041 | PASS |
| Intercept | -- | 0.406 | -- | 0.164 | PASS |
| Standard Curve (r) | 0.99 | -- | -- | 0.996 | PASS |

| KIT COMPONENTS : | | | |
|----------------------|------------|-----------|--------|
| NAME | LOT NUMBER | EXP. DATE | VOLUME |
| CaCl ₂ | N1166598 | 2019-11 | 6 ml |
| CT SP Substrate | N0177162 | 2019-01 | 12 ml |
| Factor Reagent | N0177411 | 2019-07 | 10 ml |
| CT SP Buffer, pH 7.3 | N1266893 | 2018-12 | 20 ml |
| CT SP Phospholipid | N1266894 | 2018-12 | 2 ml |

PREPARED BY: NPATEL N.m. Patel DATE: 02/14/17 2/14/17

APPROVAL SIGNATURE: DTENCZA P. Dencza DATE: 02/14/17 2/14/17